(a) “Except as provided in [paragraph (c) of this section, § 56.109(c)], informed consent shall be documented by the use of a written consent form approved by the IRB and signed [and dated] by the subject or the subject's legally authorized representative [at the time of consent]. A copy shall be given to the person signing the form.”

(b) “Except as provided in 45 CFR 46.117(c) [§56.109(c)], the consent form may be either of the following:”

“(1) A written consent document that embodies the elements of informed consent required by §46.116 [§50.25]. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed.”

“(2) A short form written consent document stating that the elements of informed consent required by §46.116 [§ 50.25] have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative in addition to a copy of the short form.” 45 CFR 46.117, 21 CFR 50.27 [FDA]

Documentation of informed consent is required unless the Institutional Review Board (IRB) approves a waiver of documentation. See HRPP Manual 6-4-D “Waiver of Documentation” for waiver of documentation criteria and procedures. Documentation of informed consent usually involves the use of a written consent form that subjects or their legally authorized representative sign and date. The consent form must contain all the elements of consent required by 45 CFR 46.116 or 21 CFR 50.25, unless a short form or an alteration of informed consent has been approved. See below for short form requirements and see the Human Research Protection Program (HRPP) Manual 6-4-B “Waiver or Alteration of Informed Consent” for alteration criteria.
The consent form, however, does not by itself constitute informed consent. The consent form should be used as a tool by which the investigator explains and discusses the research procedures with the subject, allowing the subject ample opportunity to ask questions. The researcher shall give the subject or the legally authorized representative adequate opportunity to read the consent document and have their questions addressed before it is signed. See HRPP Manual 6-4 “Informed Consent” for additional information on the consent process. The consent form must be signed and dated by the subject or the subject’s legally authorized representative, unless a waiver of documentation is granted. The IRB may require a witness to the consent process and may require that the witness also sign and date the consent form. A copy of the consent form must be given to the person signing the form (i.e. subject or legally authorized representative). Providing a copy of the consent document to the subject or their legally authorized representative serves as a reference and a reminder of information reviewed.

**Short Form Requirements**
A witness to the oral presentation is required when a short form is used. The witness must be conversant in both English and the language of the subjects for subjects who do not speak English.

A written summary (oral script) with all the elements of informed consent required by 45 CFR 46.116 or 21 CFR 50.25 is presented orally to the subject or the legally authorized representative. This written summary (oral script) must be submitted to and approved by the IRB.

The short form written consent document (short form) must include a statement that the elements of informed consent required by 45 CFR 46.116 or 21 CFR 50.25 have been presented orally to the subject or the legally authorized representative.

The subject or legally authorized representative signs and dates the short form. The witness signs and dates the short form and oral script. The person obtaining consent signs and dates the oral script.

A copy of the short form and oral script shall be given to the subject or legally authorized representative.